

DEPARTMENT OF HEALTH AND HUMAN SERVICES

July 13, 1995

Mr. Don Emlay
Vice President, Regulatory Affairs
Calgene, Inc.
1920 Fifth Street
Davis, CA 95616

Dear Mr. Emlay:

This is in regard to your genetically modified canola, about which you initiated consultation with the agency on August 17, 1992. The new canola variety has been modified to produce increased levels of lauric and myristic acids in the seed oil by expression of the enzyme 12:0 acyl carrier protein thioesterase from California bay (Umbellularia californica).

As part of bringing your consultation with FDA regarding this product to closure, you submitted a summary of your safety and nutritional assessment of the new canola variety. You also submitted information supporting your proposed new common or usual name for the oil from the new variety (Laurate Canola oil). On April 4, 1995, you discussed the data and information that support your submission with FDA. These communications were intended by Calgene to inform FDA of the steps taken to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that you have concluded that the new canola variety is not materially altered in any respect relevant to food or animal feed safety from canola varieties currently on the market and that it does not raise issues that would require premarket review or approval by FDA. Based on the compositional differences of the oil and its intended use, it is also our understanding that you have concluded that the common or usual name Laurate Canola oil is appropriate to distinguish oil from the new canola variety from traditional canola oil. All materials relevant to this consultation have been placed in a file that has been designated BNF 000025 and that will be maintained in the Office of Premarket Approval.

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Based on the information you have presented to FDA, we have no additional questions concerning this product at this time. However, as you are aware, it is Calgene's continued responsibility to ensure that foods the firm markets are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/S/

Alan M. Rulis, Ph.D.
Acting Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

cc: HFS-200 HFS-205 HFS-206 HFS-226 HFS-246 HFS-247 HFS-013
HFV-221 HFS-155 HFS-300 BNF000025